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**In the Supreme Court of the United States**

**OCTOBER TERM, 1991**

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**CHAVES COUNTY HOME HEALTH SERVICE, INC.,  
ET AL., PETITIONERS**

*v.*

**LOUIS W. SULLIVAN, SECRETARY OF  
HEALTH AND HUMAN SERVICES**

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**ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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**BRIEF FOR THE RESPONDENT IN OPPOSITION**

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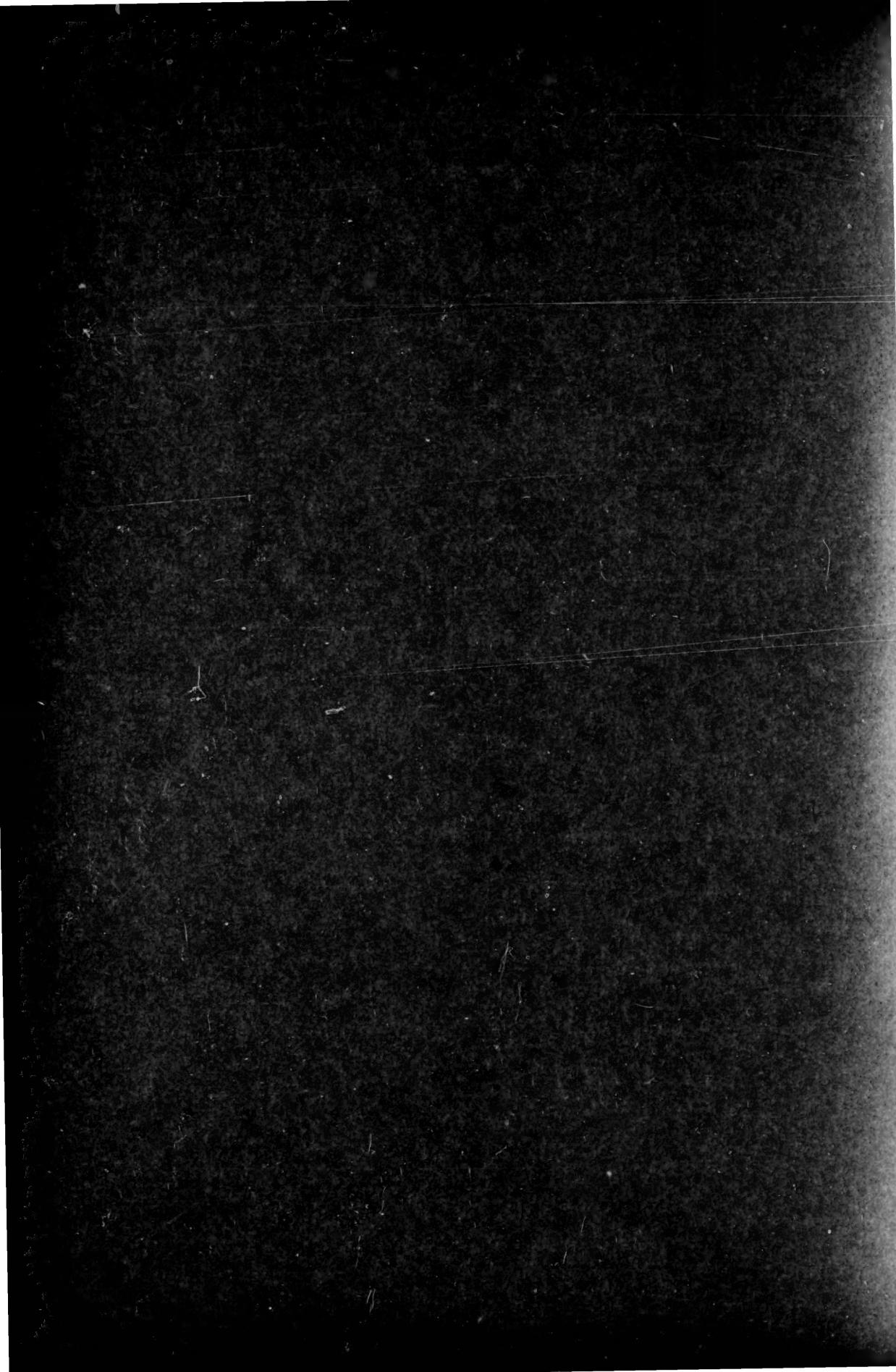
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## QUESTIONS PRESENTED

1. Whether the use of statistical sampling by the Secretary of Health and Human Services, in the exercise of his undisputed power to recoup Medicare overpayments and conduct post-payment audits of health care providers, violates the Medicare Act, Social Security Act, Title XVIII, 42 U.S.C. 1395 *et seq.*
2. Whether Health Care Financing Administration Ruling 86-1, which reaffirmed the legality of the agency's practice of using statistical sampling as a technique for recouping Medicare overpayments, is a substantive and retroactive rule subject to notice and comment rulemaking under the Administrative Procedure Act.



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v.

LOUIS W. SULLIVAN, SECRETARY OF  
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*ON PETITION FOR A WRIT OF CERTIORARI TO THE  
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**OPINIONS BELOW**

The opinion of the court of appeals (Pet. App. 1a-21a) is reported at 931 F.2d 914. The opinion of the district court (Supp. App. 1-8) is reported at 732 F. Supp. 188.

**JURISDICTION**

The judgment of the court of appeals was entered on April 26, 1991. A petition for rehearing was denied on July 26, 1991. The petition for a writ of certiorari was filed on October 24, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

**STATEMENT**

1. This case concerns the ability of the Department of Health and Human Services to recover overpayments made to health care providers under the Medicare program. Medicare, which was established

by the Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 291, provides health insurance that covers costs of hospital and related services (under Part A) and certain other supplementary services (under Part B) for aged and disabled persons. Gov't C.A. Br. 3. Under Part A, at issue here, participating health care providers that have furnished services to an eligible beneficiary submit a claim for payment to a fiscal intermediary. *Id.* at 3-4.

The intermediary reviews the claim and authorizes payment if the services provided are covered by the Act and the costs incurred are reasonable. Only coverage determinations are at issue in this case. Gov't C.A. Br. 4-5. The Act generally defines what constitutes covered services, see 42 U.S.C. 1395d, and excludes certain services from coverage, see, *e.g.*, 42 U.S.C. 1395y. In particular, the Act excludes services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury," and services constituting "custodial care." 42 U.S.C. 1395y(a)(1)(A) and (9). If the fiscal intermediary determines that a submitted claim is not for covered services, it must then determine whether, under 42 U.S.C. 1395pp(a), payment should nonetheless be made because neither the provider nor the beneficiary knew or could reasonably be expected to know that the services were not covered. The beneficiary (as opposed to the provider) is presumed to have been without such knowledge unless he received written notice informing him that the services were not covered. 42 C.F.R. 405.332, 405.334 (1989).<sup>1</sup> In contrast, providers are presumed, based, *inter alia*, upon common

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<sup>1</sup> The relevant regulations were amended and redesignated during the pendency of this litigation. See 54 Fed. Reg. 41,733-41,734 (1989). For the convenience of the Court, we will cite the regulations in their pre-redesignation form.

industry practice, to have knowledge that certain services are not covered. 42 C.F.R. 405.336 (1989).

If the beneficiary is excused from payment—and if the provider is presumed to have had the requisite knowledge—it is responsible for payment. Thus, if the beneficiary has paid the provider for the services, the government will reimburse him and seek to recover from the provider, 42 U.S.C. 1395pp(b); if the government has already paid the provider for non-covered services, those amounts will be recouped by withholding from future payments to the provider. See 42 U.S.C. 1395gg(b).

Pursuant to 42 U.S.C. 1395ff(a), which provides that claims shall be determined by the Secretary “in accordance with the regulations made by him,” a multi-layer process of review has been established for individuals who are dissatisfied with coverage and waiver determinations by a fiscal intermediary. See Gov’t C.A. Br. 6-7; 42 U.S.C. 1395ff, 1395pp. The process of review includes reconsideration by the fiscal intermediary, an evidentiary hearing before an administrative law judge (provided the amount in controversy is at least \$100), review by the HHS Appeals Council, and finally judicial review (provided the amount in controversy is at least \$1000). See *Heckler v. Ringer*, 466 U.S. 602, 605-607 (1984). Providers may seek review under the same procedures in situations where they may be liable for the cost of non-covered services and the Secretary determines that the beneficiary will not exercise his right of review. 42 U.S.C. 1395pp(d).

2. Petitioners are three home health care providers that submitted thousands of Medicare claims for services provided to eligible individuals, and received payment under Medicare Part A on those claims. Pet. App. 2a-5a. Based on a tip that two of the petition-

ers had been overbilling Medicare and on data showing that the third petitioner's claims were much higher than those of comparable providers, the Department conducted post-payment audits of the claims submitted by petitioners. *Id.* at 4a-5a. As part of these post-payment audits, the Department examined a statistically significant number of randomly selected claims for the periods in question, and examined those claims and their medical documentation to determine whether there was a pattern of billing Medicare for services that petitioners knew or should have known were not covered by the Act. *Id.* at 5a. The audits revealed that there was a statistical pattern of billing Medicare for non-covered services. Based on an extrapolation from this statistically valid evidence, the Secretary sought to recoup the overpayments made to petitioners. *Id.* at 4a-5a.

Petitioners challenged the initial non-coverage determination with respect to the individual sample claims, and they largely prevailed in the administrative review process. Pet. App. 4a-5a, 16a. The ALJ concluded that the Secretary was time-barred under applicable regulations from reopening the targeted claims of petitioner Bayonne Visiting Nurse Association, and all funds withheld from Bayonne to recoup the overpayments were repaid with interest. The overpayments that the intermediary found to have been made to petitioner Chaves County Home Health Services were reduced after an ALJ hearing from approximately \$47,000 to \$11,688.76. And the ALJ reversed a number of the overpayment determinations in the sample of claims submitted by petitioner Albuquerque Visiting Nurse Association, thereby substantially reducing the total of approximately \$138,000 in overpayments found by the intermediary. Gov't C.A. Br. 9-13.

3. a. Petitioners brought suit in federal district court, alleging that the use of statistical sampling as an auditing technique violated the Medicare Act, the Administrative Procedure Act, and their rights to due process under the Fifth Amendment.<sup>2</sup> The district court granted the Secretary's motion for summary judgment, Supp. App. 1-8, finding that "the judicial authority presently available overwhelmingly supports the proposition that statistical sampling in the readjudication of Medicare claims by HHS to determine overpayments and reimbursement liability is lawful." *Id.* at 8.

b. Petitioners appealed the district court's ruling, and the court of appeals affirmed. Pet. App. 1a-21a. The court of appeals held that the Secretary's established authority to conduct post-payment audits and recoup overpayments, which petitioners did not dispute, supported the Secretary's use of post-payment sampling audits. *Id.* at 7a-12a. Relying on established principles of statutory interpretation, see *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court of appeals first examined whether the language or structure of the Medicare Act showed that Congress had spoken directly to the issue of whether recoupment by statistically valid sampling is permissible. Finding no clear answer in the statute, the court explained that the Secretary's interpretation of the Act to allow such audits must be upheld if it is a permissible construction. Pet. App. 6a-7a. The court concluded that

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<sup>2</sup> Because petitioner Bayonne entirely prevailed in the administrative review process, it was not aggrieved by the Secretary's final decision and therefore had no right to judicial review under 42 U.S.C. 1395ff(b), which incorporates 42 U.S.C. 405(g).

the Secretary's interpretation is permissible, observing that vindicating the government's undoubted right to recoup overpayments through the device of statistical sampling "is reasonable given the logistical imperatives recognized by courts in other comparable circumstances." *Id.* at 12a.

The court of appeals rejected petitioners' argument that sampling affected the rights of beneficiaries, since sampling is not used to assess or recoup overpayments from them. Pet. App. 12a-15a. Further, the court held that allowing health care providers to challenge both the determination of non-coverage for each sample claim and the validity of the extrapolation from those determinations satisfies the providers' statutory review rights. *Id.* at 15a-17a. In the court's view, the alternative suggested by petitioners—that HHS can recoup overpayments only by reviewing every single claim and providing a separate review as to each—would impose a "daunting burden on the agency." *Id.* at 17a.

Finally, the court rejected petitioners' challenge to the legality of Health Care Financing Administration (HCFA) Ruling 86-1. That Ruling reaffirmed and explained the basis for HCFA's existing practice of using statistical sampling as an auditing technique. Pet. App. 19a-21a. The court explained that the Ruling is not the source of HCFA's authority, but rather constitutes only an explanation and reaffirmation of its practice of using post-payment sampling audits. *Id.* at 19a-20a. Accordingly, the court held that Ruling 86-1 is an interpretive ruling and, as such, was not subject to notice and comment rulemaking procedures mandated by the Administrative Procedure Act. For the same reason, the court concluded, its application

in the administrative proceeding here did not constitute retroactive rulemaking. *Id.* at 20a-21a.<sup>3</sup>

### **ARGUMENT**

The decision of the court of appeals is correct, and does not conflict with any decision of this Court or of another court of appeals. It rests on a routine application of *Chevron* principles of deference to the interpretation of the Act by the agency charged with administering the vast and complex Medicare program, and it affirms the propriety of using statistically valid sampling methodologies in the post-payment audit setting that have long been recognized in the Medicare program. In fact, such sampling was used in the leading case sustaining the Secretary's right to recoup past overpayments under Medicare—*Mount Sinai Hospital of Greater Miami v. Weinberger*, 517 F.2d 329, 333, 343, modified, 522 F.2d 179 (5th Cir. 1975), cert. denied, 425 U.S. 935 (1976)—and has not been a recurring source of controversy in the sixteen years since that case was decided. Moreover, as petitioners' own experience shows, the administrative process affords a fair and effective procedure by which a provider may challenge overpayment determinations that are based on post-payment audits of a statistically valid sample of claims.

1. Petitioners' primary contention is that the Medicare Act prohibits the Secretary from recouping

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<sup>3</sup> In an argument that they do not renew in this Court, petitioners asserted in the court of appeals that the Secretary's practice of conducting post-payment sampling audits violates due process. The court rejected that argument, noting that the statistical reliability of the process and the strong governmental interest in recouping monies that had been wrongly paid justified the practice. Pet. App. 18a-19a.

overpayments through the device of statistical sampling, and that the court of appeals therefore erred in deferring to the Secretary's contrary interpretation under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). As the court of appeals determined, however, the Act itself does not furnish an answer to the question; specifically, nothing in its language or structure compels petitioners' interpretation. Nowhere in the Act is the notion of statistical sampling addressed, and post-payment recoupment by that method is not inconsistent with other provisions of the Act providing for review of claims at the prepayment stage. Proceeding to the second step of the *Chevron* analysis, the court of appeals correctly concluded that the Secretary's construction of the Act represents a reasonable accommodation of the rights of providers not to be subject to erroneous recoupment of previously paid claims, and the Secretary's undisputed right to protect the Medicare Trust Fund by recovering monies that providers have wrongfully obtained.

a. Petitioners concede (Pet. 22) that the Secretary has authority under the Medicare Act to conduct post-payment audits in order to recoup overpayments made to health care providers. See *Mount Sinai Hospital of Greater Miami v. Weinberger*, 517 F.2d at 343; *Wilson Clinic & Hospital, Inc. v. Blue Cross*, 494 F.2d 50 (4th Cir. 1974). The government's right to recover money that it has erroneously paid is established as an element of federal common law. Moreover, this right to audit past payments and recoup overpayments is confirmed in numerous Medicare Act provisions. See Pet. App. 9a; see, e.g., 42 U.S.C. 1395y(f), 1395gg (b)(1). Petitioners contend, however, that this right of recoupment may not be exercised by examining a

statistically valid sample of a provider's claims to determine the number that were erroneously paid, and then extrapolating that figure to the relevant category of claims submitted by that provider. Pet. App. 6a.

b. As the court of appeals held, nothing in the Act either expressly allows or prohibits the Secretary's use of statistical sampling in carrying out his undisputed powers to audit and recoup. Pet. App. 12a. Contrary to petitioners' contention (Pet. 10-16), the court of appeals did not ignore 42 U.S.C. 1395ff, which governs determinations of Medicare claims. See Pet. App. 6a, 15a-16a, 17a. It noted petitioners' argument that Section 1395ff prohibits the use of sampling, and stated that it would be incompatible with the Act for statistical sampling to be used at the pre-payment stage with respect to the claims of individual beneficiaries. Pet. App. 6a. Nothing in the Act, however, expressly or impliedly deals with the question of procedures to be followed by the Secretary in recouping overpayments from providers on post-payment review. On that issue, the court of appeals held, the Act is silent.

Although petitioners contend that the Act's procedural provisions governing pre-payment coverage determinations should extend to post-payment recoupment audits, they do not explain why that is so. As the court below correctly noted, petitioners' contention fails to come to grips with the question of what "determination" is subject to review in the post-payment audit setting. See Pet. App. 15a-16a. Contrary to petitioners' contention that the Medicare Act guarantees providers a five-step review process (initial determination by the intermediary, reconsideration by the intermediary, review by an Administrative Law

Judge, review by the Appeals Council, and judicial review) for every one of the thousands of claims that may be in dispute on post-payment audit, it is reasonable to interpret the "determination" by the Secretary that is subject to review under Section 1395ff in the context of post-payment sampling audits as the findings regarding the sample claims and the validity of their extrapolation to the relevant category of the provider's claims. See Pet. App. 15a-16a.<sup>4</sup> Because the provider may contest that "determination" through the five-step review process, its statutory rights to review are fully protected. *Ibid.*

Moreover, as the court of appeals explained, the Secretary's interpretation of his recoupment authority is supported by precedent upholding the use of sampling audits to recoup overpayments in comparable circumstances. See Pet. App. 11a-12a; see, e.g., *Illinois Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982); *Michigan Dep't of Education v. United States Dep't of Education*, 875 F.2d 1196, 1204-1206 (6th Cir. 1989); *Georgia v. Califano*, 446 F. Supp. 404, 409-410 (N.D. Ga. 1977).

c. Petitioners and their *amici* assert that the enactment of Section 1395pp(d)—which extended to health care providers Section 1395ff's right to review of benefit determinations in certain circumstances, and which occurred after the events giving rise to the de-

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<sup>4</sup> Contrary to petitioners' contention (Pet. 23-24), the Secretary's use of statistical sampling is not inconsistent with the regulations promulgated under the Act. As the court of appeals held, the regulations in question, 42 C.F.R. 405.701-405.750, deal not with procedures for post-payment recoupment of overpayments, but rather with the right of providers and beneficiaries to individualized determination of benefits on initial review of claims. Pet. App. 17a.

cision in *Mount Sinai Hospital*—establishes that Congress intended Section 1395ff's procedures to apply in the post-payment setting in a manner that precludes reliance on sample audits, and instead requires separate rulings and review procedures as to each of thousands of claims.<sup>5</sup> Pet. 26 n.5; American Hospital Ass'n *et al.* Amici Br. 17. But even if the statute might reasonably be read as petitioners suggest, petitioners are incorrect that theirs is the only permissible reading. As explained above, on post-payment review involving a sampling audit, Section 1395ff is given effect by providing health care providers with a right to review of the determination that results from examination of a representative sample of claims and statistically valid extrapolation of the result to the entirety of their claims. Given the established right of the Secretary to recoup overpayments, there is no reason to conclude that enactment of Section 1395pp was intended to impose particular procedures on the exercise of that right.

2. a. Nor can petitioners establish that the Secretary's interpretation is unreasonable. Petitioners do not contend that sampling audits lead to unfair or invalid overpayment findings. A provider is furnished with a full opportunity to challenge the coverage determinations and waiver of liability findings made as to every claim in the sample group, Pet. App. 15a-16a, 8c-9c, and the extrapolation is reduced to the extent its challenge is successful. The provider may also challenge the validity of the sample, statistical assumptions, and extrapolation from the sample.

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<sup>5</sup> Petitioners are incorrect in contending (Pet. 26) that *Mount Sinai Hospital* did not take account of Section 1395pp. See *Mount Sinai Hospital*, 517 F.2d at 341 & n.22; 522 F.2d at 180 (opinion on rehearing).

*Ibid.* Petitioners have offered no reason, and we know of none, to think that this process yields anything other than fair and accurate results.<sup>6</sup> Health care providers have no entitlement to retain monies obtained from Medicare for services that they knew or should have known were not covered by the Medicare Act, and the Act should not be interpreted in a manner that would interpose significant barriers to the use of such fair procedures to recoup repayments.

b. Petitioners assert (Pet. 20) that the court of appeals' decision effectively licenses the Secretary to turn the prepayment claim review process of individual beneficiary claims into a "sham." To the contrary, the court specifically stated that post-payment sampling audits may *not* be used by HHS as a substitute for individualized pre-payment review. Pet. App. 13a-15a. Further, the court recognized that the Secretary's sampling audits are not directed against individual beneficiaries and may not be used to recoup an overpayment from an individual. *Ibid.*; see also Pet. 25.<sup>7</sup> The court merely held that where a provider

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<sup>6</sup> The reliability is enhanced by the fact that the sampling method allows both the provider and the agency to focus their attention and resources on adjudicating sample claims. The non-coverage determinations for particular claims must survive rigorous review before they are extrapolated; and no extrapolation is done unless there is a statistical pattern of wrongful payment manifested by the sample claims.

<sup>7</sup> Petitioners contend that the procedure, in effect, deprives providers of their right to recover benefits paid to individuals in certain circumstances. This argument is incorrect. The post-payment review process ensures that sample claims are decided adversely to providers only if they knew or should have known that the services at issue were not covered, a circumstance in which, by definition, providers have no recourse against individual beneficiaries. Moreover, beneficiaries have

is suspected of having a pattern of charging Medicare for services that it knows or should know are not covered by the Medicare Act, it is not inconsistent with the Act for the Secretary to supplement pre-payment review with a post-payment sampling audit.

c. Petitioners extravagantly assert (Pet. 24) that sampling audits place the entire Medicare reimbursement system "at risk." Quite the reverse is true: it is the inability to use such audits that would put the system at risk. Without use of sampling as a post-payment auditing technique, there would be no feasible means of recouping Medicare overpayments. The amount of overpayment on any particular claim may be small, but the aggregate overpayment to the provider very significant. If individual treatment of each claim on post-payment audit were required, the costs of recoupment would outstrip the amounts recovered. Cf. *Sullivan v. Everhart*, 494 U.S. 83, 94-95 (1990). Thus, the choice is essentially between using a reliable sample auditing technique or allowing providers to retain undeserved gains that were obtained contrary to law. Pet. App. 12a.

3. Finally, the court of appeals correctly rejected petitioners' arguments (Pet. 26-27) that HCFA Ruling 86-1 was subject to notice-and-comment rulemaking and that the Ruling could not be applied "retroactively" to them. Notice-and-comment rulemaking is not required for interpretive rulings. See 5 U.S.C. 553(b)(A); *American Hospital Ass'n v. Bowen*, 834

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no repayment obligation unless they have received written notice that the services at issue are not covered. In such circumstances, providers can hardly complain about lack of an opportunity for repayment if they nonetheless submitted the claims to the government for repayment despite prior notice to the beneficiary of non-coverage.

F.2d 1037, 1045 (D.C. Cir. 1987). Ruling 86-1 is nothing more than an interpretive rule setting forth the agency's view of existing law and procedures. See *Mile High Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984, 985-986 (D. Colo. 1988) (HCFA Ruling 86-1 is an interpretive rule). As the court of appeals held, "the Ruling was not the source of [the] administrative authority in these cases but merely explained and reaffirmed the Department's long-standing and well-established practice of conducting sample audits." Pet. App. 19a-20a. It follows that application of the principles set forth in the Ruling to petitioners' cases is not impermissibly retroactive. Pet. App. 19a-20a. Petitioners' legal obligations were the same both before and after the Ruling was issued.

Petitioners contend (Pet. 26) that the court of appeals erred as a factual matter in concluding that there was a long-standing practice of using sampling audits. To the contrary, as other courts have recognized as well, the practice of using sampling audits dates back at least two decades. See *Mount Sinai Hospital*, 517 F.2d at 333 (upholding Secretary's use of a sampling post-payment audit to recoup \$6.3 million); *Daytona Beach General Hosp., Inc. v. Weinberger*, 435 F. Supp. 891, 894-896 (M.D. Fla. 1977) (discussing the use of sampling audits in Medicare case in the early 1970s). Moreover, the court below correctly observed that the internal Medicare manual that petitioners themselves brought to the court of appeals' attention confirms the longstanding use of sampling audits, Pet. App. 20a, and numerous other Medicare manuals dating at least as far back as 1975 provide for sample audits to recover overpayments for non-covered services. See, e.g., *Medicare Intermediaries Manual* § 2229 & Sampling Guidelines Appen-

dix (Dec. 1975); *Medicare Intermediaries Manual* § 3799.6 (Jan. 1977); *Medicare Intermediaries Manual* § 3710.3 (June 1979), *Medicare Intermediaries Manual* § 3710.3 (Oct. 1986); *Medicare Carrier's Manual* §§ 7150-7158 (July 1989); *Medicare Intermediaries Manual* § 2229 (July 1990).<sup>8</sup> Accordingly, the decision below involves no novel principle in the administration of the Medicare program.

### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JANUARY 1992

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<sup>8</sup> For this reason, *amici* American Hospital Association, et al., err in relying (Br. 16) on the extra-record letter from former Secretary Bowen to the Comptroller General. See *id.* at 1c-3c. That letter was brought to the attention of the court of appeals, see Gov't C.A. Br. 45, and it did not affect that court's conclusion that HCFA has long followed the practice of using sampling audits to recoup Medicare overpayments. Moreover, the letter does not reflect the basis for that practice in Ruling 86-1, the manuals cited in the text above, and cases dating from the 1970s.